

### **III. Remarks**

#### **A. Status of the Application**

Claims 1 and 4-19 are pending. No claims are added, canceled, or amended by the present paper. Reconsideration of this application in light of the above amendments and the following remarks is respectfully requested. Should the Examiner find that there are any remaining issues preventing allowance of the case, Applicants request that the Examiner contact Greg Webb at 972-739-8641.

#### **B. Claim Rejections Under 35 U.S.C. § 103**

##### **1. Middleton, Reiley, Imran, and Groshong Patents**

Claims 1 and 4-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,746,451 to Middleton et al. (“Middleton patent”) in view of U.S. Patent No. 6,863,672 to Reiley et al. (“Reiley patent”) in further view of U.S. Patent No. 5,542,434 to Imran et al. (“Imran patent”) and in further view of U.S. Patent No. 5,178,625 to Groshong (“Groshong patent”).

The PTO provides in MPEP § 2131 that

“The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.”

The Examiner clearly cannot, using the Middleton, Reiley, Imran, and Groshong patents, establish a *prima facie* case of obviousness in connection to claim 1 and 4-19 for at least the following reasons.

35 U.S.C. § 103(a) provides, in part, that:

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . .”  
(emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

With respect to independent claim 1, even when combined the Middleton, Reiley, Imran, and Groshong patents fail to disclose or suggest ““a cutting cap comprising a plurality of

deformable blades sized and shaped for cutting a portion of a spinal segment, the deformable blades deformable between an orthogonally-expanded cutting configuration where the deformable blades are generally splayed outward from one another and an insertion configuration where the deformable blades extend generally parallel to one another, ... **wherein the deformable blades are positioned radially about a central opening extending through the cutting cap to allow the cutting cap to be placed over a guidewire.**”

The Office Action relies on the Middleton patent for disclosure of the cutting cap. However, it is unclear which the cutting element (120) or the cutting tips (130) of the Middleton patent is being relied upon to be the recited “plurality of deformable blades.” In that regard, p. 2 of the Office Action indicates the cutting element (120), while p.3 indicates the cutting tips (130). Regardless, neither the cutting element (120) nor the cutting tips (130) meet the recited limitations of the cutting cap. More specifically, the single cutting element (120) cannot be considered “a plurality of deformable blades” and the cutting tips appear to have the same orientation relative to one another in all orientations. Further, Applicants do not see any indication of the cutting element (120) or the cutting tips (130) being positioned radially around a central opening extending through a cutting cap. In that regard, the Middleton patent does not disclose “a central opening extending through the cutting cap to allow the cutting cap to be placed over a guidewire.” Rather, the solid cutting element (120) is attached to a solid shaft (110), preventing the cutting element from being placed over a guidewire.

Further, even when combined the Middleton, Reiley, Imran, and Groshong patents fail to disclose or suggest “**a hollow flexible shaft fixedly connected to the cutting cap**, the hollow flexible shaft including an axial lumen extending along the length of the hollow flexible shaft and **in communication with the central opening of the cutting cap** such that the hollow flexible shaft is configured to be placed over the guidewire,” as recited by claim 1. The Office Action relies on the insertion tube (14) of the Middleton patent to be the recited hollow flexible shaft. However, the insertion tube is not “fixedly connected” to a cutting cap. Rather, the cutting element (120) and its associated solid shaft (110) are introduced through the insertion tube 14. Further, since the cutting element (120) does not have an opening, the lumen of the insertion tube (14) cannot be in communication with the central opening of a cutting cap as also required.

Further still, even when combined the Middleton, Reiley, Imran, and Groshong patents fail to disclose or suggest “**a hypotube** positioned around at least a proximal portion of the hollow flexible shaft and **fixedly connected to a user graspable handle of the enucleation device**,” as recited by claim 1. The Office Action relies on the elongate tubular member (22) of the Imran patent to be the recited hypotube. However, the elongate tubular member (22) is not positioned around a hollow flexible shaft nor is it fixedly connected to a user graspable handle. Rather, as shown in Fig. 1 of the Imran patent, the guidewire (16) that includes elongated tubular member (22) is connected to a control console (18) and does not appear to include a user graspable handle.

Finally, even when combined the Middleton, Reiley, Imran, and Groshong patents fail to disclose or suggest “**a shrink tube** positioned around at least a distal portion of the hollow flexible shaft adjacent to the cutting cap, the shrink tube having a reduced outer diameter relative to the hypotube such that the shrink tube provides a bearing surface between the hollow flexible shaft and the hypotube,” as recited by claim 1. The Office Action relies on the shrink tube of the Imran patent that surrounds the elongate tubular member (22) to be the recited shrink tube. However, if the shrink tube surrounds the hypotube then the shrink tube (1) cannot have a reduced outer diameter relative to the hypotube and (2) cannot provide a bearing surface between the hollow flexible shaft and the hypotube since the hypotube is positioned around at least a proximal portion of the hollow flexible shaft.

Accordingly, for all of these reasons a *prima facie* case of obviousness cannot be established with respect to independent claim 1. Claims 4-17 require the enucleation device of claim 1. Thus, Applicants request that the § 103 rejection of claims 1 and 4-17 over the Middleton, Reiley, Imran, and Groshong patents be withdrawn.

With respect to independent claim 18, even when combined the Middleton, Reiley, Imran, and Groshong patents fail to disclose or suggest:

18. An enucleation device comprising:
  - a proximal end;
  - a distal end comprising a cutting cap sized and shaped for cutting a portion of a spinal segment, the cutting cap comprising a plurality of deformable blades comprising a shape memory alloy, wherein the deformable blades are deformable between an orthogonally-expanded cutting configuration where the deformable blades are generally splayed outward from one another about a central opening extending through the cutting cap to allow the

cutting cap to be placed over a guidewire and an insertion configuration where the deformable blades extend generally parallel to one another and parallel to a longitudinal axis of the central opening, wherein the shape memory alloy of the deformable blades is processed such that the orthogonally-expanded cutting configuration is a neutral position for the deformable blades and the insertion configuration is a deformed position for the deformable blades such that when the deformable blades are not deformed the deformable blades return to the orthogonally-expanded cutting configuration;

a hollow flexible shaft extending between the proximal end and the cutting cap, the hollow flexible shaft fixedly attached to the cutting cap and including an axial lumen extending along the length of the hollow flexible shaft in communication with the central opening of the cutting cap such that the hollow flexible shaft is configured to be placed over the guidewire;

a hypotube positioned around at least a proximal portion of the hollow flexible shaft and fixedly connected to a user graspable handle of the enucleation device;

a shrink tube positioned around at least a distal portion of the hollow flexible shaft adjacent to the cutting cap, the shrink tube providing a bearing surface between the hollow flexible shaft and the hypotube; and

a motor adapter positioned adjacent to the proximal end, the motor adapter configured to connect the hollow flexible shaft to a motor drive configured to rotate the shaft to cause rotation of the cutting cap;

where the plurality of deformable blades can cut material in a space when the blades are not deformed; and

where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material.

In that regard, the Middleton, Reiley, Imran, and Groshong patents simply do not disclose or suggest an enucleation device that includes a cutting cap, hollow flexible shaft, hypotube, user graspable handle, and shrink tube having all of the features recited in claim 18. In that regard, claim 18 recites some features that are identical or similar to those discussed above with respect to independent claim 1. Accordingly, for similar reasons a *prima facie* case of obviousness cannot be established with respect to independent claim 18. Claim 19 requires the enucleation device of claim 18. Thus, Applicants request that the § 103 rejection of claims 18 and 19 over the Middleton and Reiley patents be withdrawn.

#### **IV. Conclusion**

It is believed that all matters set forth in the Office Action have been addressed and that all of the pending claims are in condition for allowance. Accordingly, an indication of allowability is respectfully requested.

The Office Action contains characterizations of the claims and the related art to which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in this or any other Office Action.

As noted above, should the Examiner find that there are any remaining issues preventing allowance of this case, Applicants request that the Examiner call the undersigned attorney in an effort to resolve any such issues.

Respectfully submitted,



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I hereby certify that this correspondence is being filed with the United States Patent and Trademark Office via EFS-Web on August 23, 2010.

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